

**UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF TENNESSEE
WESTERN DIVISION**

United States of America ex rel. Richard LARDNER,)	
)	
Relator,)	Civil Action No. 2:17-cv-02013-JPM-egb
)	
v.)	
)	
SMITH & NEPHEW INC., and METRO)	
MEDICAAL EQUIPMENT & SUPPLY,)	
INC.,)	
)	
Defendants.)	

**RELATOR’S MEMORANDUM IN OPPOSITION TO DEFENDANT SMITH &
NEPHEW’S MOTION TO DISMISS**

I. INTRODUCTION

Defendant Smith & Nephew Inc.’s (S&N) Motion to Dismiss improperly seeks application of a Rule 9(b)’s particularity requirement demanding more than required to win at trial. S&N also mischaracterizes relevant regulations and interpretive cases to lure this Court into condoning its use of Metro Medical Equipment & Supply, Inc. (MM) as a sham front to procure contracts statutorily set-aside for small businesses. Finally, S&N mischaracterizes the Complaint and the law to wrongly assert Lardner has not adequately alleged a second scheme arising from its fraudulent misrepresentation that all of its products are made in the U.S.A.

II. FACTS AND LEGAL PREDICATE

The crux of this case is that, under the Small Business Act and its implementing regulations, micro-acquisitions (defined as those with an anticipated dollar value exceeding \$3,500 but not over \$150,000) are “automatically reserved exclusively for small business concerns and shall be set aside for small business unless the contracting officer determines there is not a reasonable expectation of obtaining offers from two or more responsible small business concerns that are competitive in terms of market prices, quality, and delivery.” (¶¶ 34-35¹, citing FAR § 19.502-2). As a sales representative for S&N (¶ 15), Lardner observed first-hand that, for such governmental micro-acquisitions, S&N pre-negotiated the sale and then used MM as a sham front to submit the “winning” bid for the initial purchase of its TRUCLEAR system, and then dealt directly with the governmental purchaser for the sale and delivery of tens of thousands of dollars in related disposables during the life of the equipment. In addition, knowing that the Buy American Act applied to these governmental acquisitions, S&N and MM misrepresented that S&N’s Fluid Management System (“FMS”) was made in the U.S., when it was made in Germany. (¶ 130.)

¹ “(¶¶ ____)” refers to paragraphs in Lardner’s Complaint, filed January 11, 2017.

The TRUCLEAR System is a suite of medical equipment designed for hysteroscopies, which is the resection (*i.e.*, removal) of intrauterine abnormalities. (¶¶ 4, 63-64.) A complete TRUCLEAR System for operating room use includes a tissue removal system, called a morcellator, paired with a Hysteroscope Set to visualize inside the uterus, plus a Hysteroscopic Fluid Management System (“FMS”), also sold separately, to dilate the uterus. (¶¶ 66-69.)

Because the TRUCLEAR System costs about \$38,000 (¶ 87 and n.10), depending on configuration, it is subject to the automatic small business set-aside requirements for purchases greater than \$3,500. (¶¶ 34-35 citing FAR § 19.502-2). Therefore, Government-owned health care providers, such as hospitals run by the Veterans Administration (VA), were required to purchase hysteroscope systems such as TRUCLEAR from valid small businesses. (*Id.*)

As a publicly traded international company with over 15,000 employees (including over 5,500 in the U.S.) and generating more than \$4.6 billion in revenue for 2015, S&N could not qualify as a small business to directly sell its TRUCLEAR System to government purchasers. (¶ 16.) To get around this small business set-aside law, S&N conspired with MM to improperly use MM’s claimed status as a small, disadvantaged, woman and Asian-Pacific American owned business, which has only about ten employees. (¶¶ 3, 17, 79.) The Small Business Administration (“SBA”) regulations and the Federal Acquisition Regulations (“FAR”) define a “small business concern” as “a concern, *including its affiliates*, that is independently owned and operated, not dominant in the field of operation in which it is bidding on government contracts, and qualified as a small business under the criteria in 13 C.F.R. § 121 and size standards in this solicitation.” (¶ 42 citing FAR § 52.213-3(a) (emphasis added), and 13 C.F.R. § 121.103(a)(6) and (b)(4)(i).) In the present case, the nature of MM’s relationship with S&N, including S&N’s control over MM,

qualified them as “affiliates,” thereby disqualifying MM from bidding on and being awarded micro-acquisition contracts set-aside for small businesses.

In the present case, Relator Lardner personally observed that S&N had absolute control over every aspect of the sales and distribution process to VA hospitals, and that MM was only used to submit the proposal to, and receive payment from, each VA hospital. (¶¶ 62, 75-76, 80, 92.) S&N’s sales representatives—such as Lardner himself—negotiated with each VA hospital in advance of their issuance of a request for proposal (¶ 80-83), and then MM would “win” the proposal at the price S&N had already negotiated (¶¶ 84-86). Once the contract was procured, S&N’s personnel delivered and set-up the TRUCLEAR System (¶ 76), and the Government purchaser paid MM who kept a cut of the proceeds and remitted the bulk of the funds to S&N. (¶¶ 4, 98.) MM rarely, if ever, had any interaction directly with a Government purchaser, let alone a substantive interaction in which it exercised any business judgment or control over the process. (¶ 81.) All pricing and all discounts were negotiated and approved solely by S&N, including for example, and without limitation, the VA Palo Alto Health Care System (which Lardner himself negotiated) and the VA Puget Sound Health Care System upon which Lardner modeled the pricing for the VA Palo Alto. (¶¶ 87-91.) In short, MM added no material value to the transactions. (¶ 92.)

Notwithstanding various badges of “affiliation,” including S&N’s execution of all marketing, sales, negotiation, pricing, delivery and set-up functions, S&N’s complete control over MM’s ministerial function of submitting pre-negotiated bids and processing payments (¶¶ 80-83), the fact MM never took possession of the goods, and the fact MM could not conceivably have taken title to the goods because they were delivered to government purchasers by S&N rather than a common carrier (¶ 76), MM represented itself to government purchasers as a small business entitled to bid upon and win micro-acquisition small business set aside contracts for the

TRUECLEAR System. (¶¶ 77-78.) Specifically, in its registration on the SBA’s System for Award Management (SAM), a requisite for doing business with the government (¶ 45), MM listed itself as a small business. (¶ 77.) Indeed, the SBA’s Dynamic Small Business Search (DSBS), a database of small businesses generated from the SAM data (¶ 52), shows MM is registered as a self-certified small business. (¶ 77.) Furthermore, each of MM’s bids on the government contracts was required to include representations and certifications about its small business status (*i.e.*, lack of affiliation), made through its record on SAM or in the actual bid. (¶ 56, citing FAR § 52.212-3.)

III. ARGUMENT

A. Relevant Legal Standards under Rules 12(b)(6), 9(b) and 8(a)

A motion to dismiss under Rule 12(b)(6) calls upon the Court to “determine whether a cognizable claim has been pled,” while “constru[ing] all well-pleaded facts liberally in favor of the [plaintiff].” *U.S. ex rel. Meyer v. Kempf Surgical Appliances, Inc.*, No. 1:11-cv-00111, 2013 WL 1438025, *2 (S.D. Ohio Apr. 9, 2013). The motion is denied if the complaint “contain[s] sufficient factual matter, accepted as true, to state a claim to relief that is plausible on its face.” *Courie v. Alcoa Wheel & Forged Products*, 577 F.3d 625, 629-30 (6th Cir. 2009). However, “[t]he plausibility standard is not akin to a ‘probability requirement,’” *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009), and “simply calls for enough fact to raise a reasonable expectation that discovery will reveal evidence of illegal [conduct].” *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 556 (2007). This analysis is a “context-specific task that requires the reviewing court to draw on its judicial experience and common sense.” *Iqbal*, 556 U.S. at 679.

FCA cases must also be pled with Rule 9(b) particularity. *U.S. ex rel. SNAPP, Inc.*, 532 F.3d 496, 502-503 (6th Cir. 2008) (*SNAPP I*). The Sixth Circuit admonishes that “Rule 9(b) should be interpreted in harmony with Rule 8” and “should not be read to defeat the general policy of

‘simplicity and flexibility’ in pleadings contemplated by the Federal Rules.” *Id.* at 503. Rule 8(a) only requires a “short and plain statement of the claim showing that the pleader is entitled to relief,” to which Rule 9(b) adds “a party must state with particularity the circumstances constituting fraud or mistake.” Fed. R. Civ. P. 8(a) and 9(b). Importantly, Rule 9(b) does not require plaintiff “to actually *prove* his allegations.” *U.S. ex rel. Prather v. Brookdale Sr. Living Cmtys, Inc.*, 838 F.3d 750, 771 (6th Cir. 2016) (emphasis in original). In short, “Rule 9(b) exists predominantly for the same purpose as Rule 8: to provide a defendant fair notice of the substance of a plaintiff’s claim in order that the defendant may prepare a responsive pleading.” *SNAPP I*, 532 F.3d at 504.

Thus, a proper Rule 9(b) analysis is tailored to the elements of the causes of action alleged. Here, Lardner pleads under the FCA’s first three provisions, which impose liability upon anyone who: 1) “presents or causes to be presented a false or fraudulent claim”; 2) “makes, uses or causes to be made a false record or statement material to a false or fraudulent claim”; and 3) conspiracy to commit the same. 31 U.S.C. §§ 3729(a)(1)(A), (B) & (C). The Sixth Circuit has distilled the elements for the first two provisions as requiring a relator to plead: [1] “that the defendant [made] a false statement or created a false record [2] with actual knowledge, deliberate ignorance, or reckless disregard for the truth or falsity of the information; [3] that the defendant ... submitted a claim for payment to the federal government; ... and [4] that the false statement or record [was] material to the Government’s decision to make the payment sought in the defendant’s claim.” *U.S. ex rel. Sheldon v. Kettering Health Network* 816 F.3d 399, 408 (6th Cir. 2016) (*quoting, in part, U.S. ex rel. SNAPP, Inc. v. Ford Motor Co.*, 618 F.3d 505, 509 (6th Cir. 2010) (“*SNAPP II*”)).

To address the FCA’s “false record or statement” element, the Sixth Circuit’s Rule 9(b) analysis borrows the standard applied to common law and securities cases, requiring: (1) the time, place, and content of the alleged misrepresentation, (2) the fraudulent scheme, (3) the defendant’s

[scienter]², and (4) the resulting injury.” *U.S. v. SavaSeniorCare, LLC*, Nos. 3:11-00821, 3:15-00404, 3:15-01102, 2016 WL 5395949, *13 (M.D. Tenn. Sep. 27, 2016). To address the FCA’s “false or fraudulent claim” element, the Sixth Circuit requires allegations of the details of the scheme coupled with either details of actual claims submitted to the government or “facts which support a *strong inference* that a claim was submitted.” *U.S. ex rel. Chesbrough v. VPA, P.C.*, 655 F.3d 461, 471 (6th Cir. 2011) (emphasis added). The Supreme Court has addressed the “strong inference” standard, holding that it does not mean “irrefutable.” *Tellabs, Inc. v. Makor Issues & Rights, Ltd.*, 551 U.S. 308, 324 (2007).³ The Supreme Court emphasized that under such a standard, a plaintiff is not forced to plead more than she would be required to prove at trial.” *Id.* at 328. Applied to FCA cases, a strong inference that a false or fraudulent claim was submitted to the Government occurs where it follows closely from the details of the scheme, is cogent, and is at least as compelling as any opposing inference one could draw from the facts alleged.

² The FCA does not require specific intent, only actual knowledge, or intentional or reckless disregard for the truth or falsity of the information. 31 U.S.C. § 3729(b)(1).

³ In that case, the Court interpreted an amendment to the Private Securities Litigation Reform Act (“PSLRA”) requiring plaintiff to plead “with particularity facts giving rise to a strong inference that defendant acted with the requisite state of mind.” *Id.* at 314. Overruling a Sixth Circuit decision, the Supreme Court explained:

The strength of an inference cannot be decided in a vacuum. The inquiry is inherently comparative: How likely is it that one conclusion, as compared to others, follows from the underlying facts? To determine whether the plaintiff has alleged facts that give rise to the requisite “strong inference” of scienter, a court must consider plausible, nonculpable explanations for the defendant’s conduct, as well as inferences favoring the plaintiff. *The inference that the defendant acted with scienter need not be irrefutable*, i.e., of the “smoking-gun” genre, or even the “most plausible of competing inferences.” *Fidel*, 392 F.3d at 227 (quoting *Helwig v. Vencor, Inc.*, 251 F.3d 540, 553 (6th Cir. 2001) (en banc)).
 * * * *A complaint will survive, we hold, only if a reasonable person would deem the inference of scienter cogent and at least as compelling as any opposing inference one could draw from the facts alleged.*

Id. at 324 (emphasis added) (overruling *Helwig*, *supra*, to the extent it held a “strong inference” standard required pleading the “most plausible of competing inferences” (overruling recognized by *Ricker v. Zoo Entm’t, Inc.*, 534 F. App’x. 495, n.3 (6th Cir. 2013))).

B. Lardner Has Adequately Pled that “False or Fraudulent” Claims for Payment Were Actually Submitted to the Government

Unlike some schemes affecting a broad range of payors, here the scheme targeted only Government payors pursuant to government contracts. Hence, it is inconceivable that claims were not submitted to the Government, unless Defendants’ defense is that they provided the goods for free. Moreover, the chart at ¶ 100 lists 17 contracts awarded to MM for goods that would have been supplied to the purchaser directly by S&N, including the August 16, 2011 contract, which is the Palo Alto transaction described in detail at ¶¶ 93-96. It also includes contracts for S&N’s FMS manufactured in Germany, but which, as discussed below, Defendants fraudulently represented as being manufactured in the U.S. Given the laws at issue and the fraudulent inducement nature of this case, this list of transactions is more than adequate to support a strong inference that ineligible claims for payment were submitted to the Government. *Meyer*, 2013 WL 1438025, at *4 (examples of dates of medical services to government beneficiaries identified by initials was sufficient).⁴ Hence, the real focus here is on the scheme alleged in the Complaint.

Contrary to S&N’s assertions, the strong inference is not required to be based on Lardner’s first-hand, personal knowledge. *U.S. ex rel. Eberhard v. Physicians Choice Laboratory Services, LLC*, 642 Fed. Appx. 547, 553 (6th Cir. 2016) (stating that a strong inference that a claim has been

⁴ The cases cited by S&N where Courts demanded greater reliability that claims were actually submitted to the Government, such as personal knowledge, are distinguishable in one of two ways. First, as situations where the misconduct did not solely target Government payors, such as a broad scheme by health care providers that could have affected only private payors. *See e.g., U.S. ex rel. Hirt v. Walgreen Co.*, 846 F.3d 879, 882 (6th Cir. 2017) (owner of competing pharmacy lacked personal knowledge about whether Walgreen provided gift cards to Medicare and Medicaid recipients, filled their prescriptions, and then billed the Government). Second, as situations where, even if the Government was the sole payor, the false records generated inside the defendant company might not have been included in paperwork submitted to the Government. *See, e.g., U.S. ex rel. Marlar v. BWXT Y-12, L.L.C.*, 525 F.3d 439, 446 (6th Cir. 2008) (Rule 9(b) not satisfied where nurse at nuclear power facility was aware of internal reports of work-related injuries and illnesses, but could not allege what was actually submitted to the DOE).

submitted can be based “either on the basis of ‘personal knowledge’ *or otherwise*” (emphasis added) (quoting *Chesbrough*, 655 F.3d at 470-72); *Sheldon*, 816 F.3d at 413 (relator’s conversations with defendants’ employees was reliable “personal knowledge” in satisfaction of Rule 9(b) standard). Courts have also found a strong inference that a claim was submitted to the Government when it is clear that the Defendant is on notice of the claims against it, that is, where data concerning even some of the false or fraudulent claims “would serve no further purpose consistent with Rule 9(b) because defendants are on notice that the basis of the alleged fraud in each claim is the relationship between the defendants, not anything unique to a particular claim.” *Meyer*, 2013 WL 1438025, at *4 (citation and quotation omitted).

The fact that the claims submitted were “false or fraudulent” is driven by the operative legal theory of fraudulent inducement, which the Supreme Court has held necessarily taints all claims submitted under such an improperly obtained contract. In these cases, Rule 9(b) analysis is not focused on the claims for payment submitted under the contract, but rather “on the false or fraudulent statements which induced the government to enter into the contract at the outset.” *U.S. ex rel. Simpson v. Bayer Healthcare*, 732 F.3d 869, 876 (8th Cir. 2013) (under a fraud in the inducement theory need not show that the claims were “false or fraudulent in and of themselves”). This is because such a deceitful inducement

... did not spend itself with the execution of the contract. Its taint entered into every swollen estimate which was the basic cause for payment . . . The initial fraudulent action and every step thereafter undertaken, pressed ever to the ultimate goal—payment of government money to persons who had caused it to be defrauded.

Id. at 876 (quoting *Marcus v. Hess*, 317 U.S. 537, 543-44 (1943)); *see also U.S. v. United Techs. Corp.*, 626 F.3d 313, 320 (6th Cir. 2010) (“False statements underlying ... contracts generate a stream of related invoices and cause the government to pay all the invoices related to the contract.”)

Here, Lardner alleged that S&N, through MM, fraudulently obtained micro-acquisition small business set-aside contracts by misrepresenting, and/or causing MM to misrepresent, that MM was a bona fide small business qualified to bid on, procure and receive payment under such contracts. (¶¶ 4, 7, 51, 62, 75, 97, 110.) It follows—as a matter of law—that all claims for payment under those contracts were tainted by the fraudulent inducement and wholly ineligible for payment because the Government failed to receive the benefit of its bargain for directing purchasing dollars to small businesses to further their development. *See U.S. v. R.J. Zavoral & Sons, Inc.*, No. 12-668, 2014 WL 5361991, at *15 (D. Minn. Oct. 21, 2014) (“the Government is entitled to argue to the jury that it received no value under the Contract,” where defendant misrepresented its qualification to participate in SBA program); *see also, U.S. ex rel. Longhi v. U.S.*, 575 F.3d 458 (5th Cir. 2009) (misrepresentations to SBA concerning experience and qualifications to obtain grants compelled FCA actual damages equal to the government payments).

C. Lardner Has Adequately Pled that S&N Improperly Used MM as a “Sham” Front to Obtain Contracts Set Aside for Small Businesses

1. Lardner Has Sufficiently Pled that MM Is a Sham “Small Business Nonmanufacturer” with Respect to the Contracts at Issue

A company qualifies as “small business nonmanufacturer” only if it: “(i) Does not exceed 500 employees; (ii) Is primarily engaged in the retail or wholesale trade and normally sells the type of item being supplied; (iii) Takes ownership or possession of the item(s) with its personnel, equipment or facilities in a manner consistent with industry practice; and (iv) Will supply the end item of a small business manufacturer, processor or producer made in the United States, or obtains a waiver of such requirement.” 13 C.F.R. § 121.406(b). Lardner’s allegations support a strong inference that, with respect to the government contracts fulfilled by S&N, MM cannot satisfy the

first, third and fourth requirements. Since the first and fourth requirements also pertain to “affiliation” determinations, those points are addressed in Subsection 2 below.

As to the third requirement, Lardner alleged that MM never took title or possession of the goods because they were delivered to government purchasers by S&N personnel. (¶¶ 76.) As case law cited by S&N concedes, the only way MM could take title to the goods would be if it had assumed the risk of loss for the goods by acting as a drop shipper who hired a commercial carrier to pick-up the goods from S&N and deliver them to Government purchasers. S&N Br. at 9 and 10 (citing *Size Appeal of: Wear Mark, Inc. d/b/a/ All Seasons Apparel, Appellant Re: A2z Promo Zone*, SBA No. SIZ-5397, 2012 WL 4359132, at *8 (S.B.A. Sep. 12, 2012)).

Attempting to avoid this conclusion, S&N misconstrues Complaint ¶¶ 97-98 to suggest a level of ambiguity failing to foreclose the possibility MM was a drop shipper. Br. at 1 & 10. S&N’s argument is premised upon ignoring Complaint ¶ 76, where Lardner alleged that the goods were delivered by S&N personnel, thereby foreclosing the possibility they were delivered by a common carrier. Paragraphs 97-98 relate to the specific example of a contract for the VA Palo Alto Health Care System, as to which Lardner alleged that the goods were “most likely” shipped to the client from S&N’s Oklahoma facility. Contrary to S&N’s argument, the phrase “most likely” is intended to indicate which of the two S&N distribution facilities the goods likely came from, but does not nullify Paragraph 76’s allegation that all goods were delivered by S&N personnel. Hence, S&N’s argument runs afoul of the requirement to construe all allegations in Lardner’s favor.

2. Lardner Adequately Pleaded that S&N and MM Are Affiliates, Making Both Ineligible to Bid on Small Business Set-Aside Contracts for the TRUCLEAR System

The essence of Lardner’s claim under 31 U.S.C. § 3729(a)(1)(A)-(B) is that neither S&N nor MM could alone bid on or procure government contracts for the TRUCLEAR system, since

S&N was too large to bid on small business set-asides, and MM did not have the capability, resources, or distribution authority without S&N. S&N generally did not sell through third-party distributors, making its relationship with MM a deviation from its usual practice—a deviation designed to access otherwise inaccessible small business set-aside contracts. This was necessitated by the cost of the TRUCLEAR system, which mandated bids to be limited to small businesses.

S&N correctly states that Lardner alleges that MM was ineligible to bid on small business set-asides because it was affiliated with S&N, but incorrectly analyzes the factual bases establishing affiliation. S&N Mem. at 11-13. Since MM represented that it had 8-11 employees (¶ 79), standing alone it would readily meet the small business employee count criterion. However, the regulations require counting the employees of the concern “*including its affiliates.*”⁵ 48 C.F.R. § 52.212-3(a) (emphasis added). If an entity is *affiliated* with another entity, then the entity seeking small business status must add to its employee count the employees of the other entity. (*Id.*) Accordingly, if MM is affiliated with S&N for purposes of TRUCLEAR sales, then its employee count would be in the multiple thousands.

Because MM is a distributor of products it did not manufacture, it is subject to designation as a nonmanufacturer, and can be designated as “small” only if it meets certain requirements. 13 C.F.R. § 121.406(b); *see* Complaint at ¶ 44. The most important of those requirements for purposes of this case is that its employee count does not exceed 500, and that it delivers the product of a small business unless it obtains a waiver. 13 C.F.R. § 121.406(b)(1)(i)&(iv); *see also* 48 C.F.R. § 52.212-1(a) (identifying small business size standard for nonmanufacturer as 500 employees).

⁵ “Small business concern means a concern, including its affiliates, that is independently owned and operated, not dominant in the field of operation in which it is bidding on Government contracts, and qualified as a small business under the criteria in 13 CFR Part 121 and size standards in this solicitation.” 48 C.F.R. § 52.212-3.

Accordingly, whether MM is affiliated with S&N for purposes of the TRUCLEAR system transactions is dispositive of whether the bids for government contracts for the systems are fraudulent in claiming that MM is a small business.

“Concerns and entities are affiliates of each other when one controls or has the power to control the other It does not matter whether control is exercised, so long as the power to control exists.” 13 C.F.R. § 121.103(a)(1). Control may be based upon dependence, including “such dependence that the [claimed small business] cannot exercise independent business judgment without great economic risk.” 13 C.F.R. § 124.106(g)(4). An affiliation determination must consider all relevant factors, including contractual relationships, management, and previous relationships with another concern. 13 C.F.R. § 121.103(a)(2). Moreover, “the SBA will consider the totality of the circumstances, and may find affiliation even though no single factor is sufficient to constitute affiliation.” 13 C.F.R. § 121.103(a)(5).

S&N erroneously asserts Lardner lacks personal knowledge about the relationship between the Defendants and therefore has no knowledge of any control elements. To the contrary, as a sales representative involved in selling the TRUCLEAR system to Government entities, including VA hospitals, Lardner observed first-hand the interactions between S&N and MM with respect to those transactions.⁶ The particular facts demonstrating S&N’s control of the transactions, and therefore affiliation, are more extensive than admitted by S&N (S&N Mem. at 11-12), and include:

- MM had no control over the sales of the TRUCLEAR systems; that work was done by S&N sales representatives (¶¶ 76, 80, 110);
- Only S&N sales representatives interacted with government purchasers to initiate solicitations (¶¶ 74, 76);

⁶ Here, how MM interacted with other vendors, or how it was managed is irrelevant. The only pertinent transactions are those between MM and S&N related to sales of the TRUCLEAR system.

- MM only prepared product quotations and only bid on TRUCLEAR systems when directed by S&N (¶¶ 4, 76, 81, 84, 86, 87-91, 93-96);
- MM priced the systems as directed and approved by S&N; it had no authority to discount prices (¶¶ 4, 81, 82, 83, 86, 87-91, 93-96, 110);
- S&N managed the physical delivery of the systems (¶ 76, 97, 110);
- S&N set up the systems once purchased (¶¶ 4, 76, 110); and
- S&N sales representatives provided ongoing procedure use support and training (¶ 76).

Accordingly, for purposes of this motion to dismiss, Lardner has offered particular facts making it plausible that S&N exercised sufficient control over MM with respect to sales of TRUCLEAR systems such that the two entities were affiliated for purpose of determining MM's non-eligibility to bid on small business set-asides for the systems. MM may independently distribute other products, but sales of the TRUCLEAR system would not happen without S&N's control.

Finally, S&N wrongly asserts the Complaint assumes that a nonmanufacturer must take physical possession of a product, and that this is the only reason Lardner claims MM did not qualify as a small business nonmanufacturer. S&M Mem. at 7-8, 10-13. In ¶ 44 of the Complaint Lardner makes it clear that four elements go into the nonmanufacturer designation. Since the list is conjunctive, all four must be met for a business to be a small business nonmanufacturer. However, for purposes of this case, the first element, that the business not exceed 500 employees is dispositive because MM is affiliated with S&N for purposes of the TRUCLEAR transactions. Once affiliation is established by exceeding the employee count, meeting the other requirements is irrelevant. Accordingly, the Complaint states that affiliation is the primary driver of the fraud. (*See e.g.*, ¶¶ 4, 6, 112, 114.) That said, Lardner asserts that S&N also fails to meet the third and fourth elements because in these transactions it does not take ownership or possession of the systems and is delivering the product of a large, rather than small, manufacturer.

D. Lardner's Country of Origin Claim Satisfies both 12(b)(6) and Rule 9(b) Particularity

The Buy American Act applies to purchases and contracts which exceed the micro-acquisition threshold of \$3,500, and requires the place of manufacture to be in the United States. (¶¶ 126-129 citing 41 U.S.C. § 8302.); 48 C.F.R. § 25.101(b). In order to qualify as a domestic manufactured end product, it must be both “manufactured in the United States” and its “cost of domestic components must exceed 50 percent of the cost of all the components.” 48 C.F.R. § 25.101(a). For goods manufactured in other countries using parts from various countries, the “[p]lace of manufacture means the place where an end product is assembled out of components,” and “[i]f a product is disassembled and reassembled, the place of reassembly is not the place of manufacture. 48 C.F.R. § 52.225-18(a). In the present case, Defendants fraudulently induced governmental purchases of S&N’s Fluid Management System (FMS) and related components by falsely representing they were manufactured in the United States. (¶¶ 6-7; 119-131.) As previously noted, fraudulent inducement renders all ensuing claims ineligible for payment.

In each of the particular contracts referenced by Lardner (¶¶ 99-100, 121), the place of manufacture is a required field in the government contract database. When a product contains substantial foreign components, the place of manufacture indicates whether the contract is still technically a U.S. contract (Buy American Act).⁷ This field represents whether the end products procured by the contract are manufactured inside or outside the U.S. in accordance with the Buy American Act. (¶126; *See also* § 4.10.6 *GSA Federal Procurement Data System-Next Generation (FPDS-NG)*, Data Element Dictionary (Ver. 1.4 2017).) Along with the specific August 16, 2011

⁷ *GSA Federal Procurement Data System-Next Generation (FPDS-NG)*, Data Element Dictionary (Ver. 1.4 2017). *See* FRE 201 (allowing judicial notice of facts “so universally known that they cannot reasonably be the subject of dispute”).

(the Palo Alto Solicitation ¶¶ 93-96) and October 31, 2013 contracts (¶ 100) that specifically reference components of the FMS in the product descriptions, Lardner is aware that on January 9, 2017 MM was awarded a contract for the FMS (Procurement Identifier: VA26317P0259) by the Department of Veterans Affairs which was then obligated to pay \$89,118.28 as a result of the contract award. This screen shot of the contract⁸ (which is representative of the other contracts identified by Lardner) illustrates Defendants' false representation that the FMS was manufactured in the United States.

Product Or Service Information	
Product/Service Code:	6515 Description: MEDICAL AND SURGICAL INSTRUMENTS, EQUIPMENT, A
Principal NAICS Code:	339112 Description: SURGICAL AND MEDICAL INSTRUMENT MANUFACTURIN
Bundled Contract:	Not a bundled requirement ▼
DOD Acquisition Program:	
Country of Product or Service Origin:	USA UNITED STATES
Place of Manufacture:	Mfg in U.S.

However, Lardner was aware that the FMS was manufactured in Germany and then shipped to the United States. (¶¶ 123-124, 130.). S&N is also well aware of this fact, as it specifically sought a declaration from World of Medicine (W.O.M.) stating W.O.M. manufactured the FMS (to the exclusion of any system manufacturing for competitors of S&N).⁹ Accordingly, Defendants' misrepresentation of the true place of manufacture induced the government to enter into contracts it would not have otherwise, and the fraud in the inducement theory establishes that the payments received by Defendants as a result of those contracts are fraudulent as well. Lardner's

⁸ This Circuit recognizes a public records exception to the principle that a complaint should be assessed without considering matters outside the pleadings. *Jones v. City of Cincinnati*, 521 F.3d 555, 562 (6th Cir. 2008) (citing *Jackson v. City of Columbus*, 194 F.3d 737, 745 (6th Cir. 1999)).

⁹ Lardner's knowledge is based on document he received in May 2007, during the regular course of performing his job with S&N, which is a declaration signed by Marc Engelhardt, a W.O.M. employee in Germany, stating that W.O.M. manufactures the Fluid Management System.

Complaint satisfies Rule 12(b)(6).

As to Rule 9(b), Lardner's Complaint (§§ 119-131) clearly identifies Defendants' fraudulent inducement scheme with sufficient particularity, including the identification of relevant contracts that necessarily led to the submission of false or fraudulent claims to the Government. Rule 9(b) "is not designed to force a plaintiff to prove [his] case in the complaint, but simply to give adequate notice to the defendants and ensure there is some basis for the allegations." *U.S. v. Assocs. in Eye Care, P.S.C.*, No. 13-27-GFVT, 2014 U.S. Dist. LEXIS 15724, 2014 WL 414231, at *7 (E.D. Ky. Feb. 4, 2014). Defendant is hard pressed to claim it could not prepare a responsive pleading to these allegations.

The fact that Lardner did not have access to the actual claims for payment does not require dismissal. *U.S. ex rel. Bledsoe v. Cmty Health Sys., Inc.*, 501 F.3d 493, 504 n.12 (6th Cir. 2007) (opining Rule 9(b) could still be satisfied "where a relator demonstrates that he cannot allege the specifics of actual false claims that in all likelihood exist, and the reason that the relator cannot produce such allegations is not attributable to the conduct of the relator"). As S&N points out, Lardner was not an employee of MM. Moreover, since the scheme only targeted Government purchasers, this is no "fishing expedition." Lardner has demonstrated, based on specific documentation given to him, first-hand knowledge, and specifically identified contracts, that Defendants misrepresented the place of manufacture as in the United States, knowing it was actually manufactured in Germany by W.O.M. Accordingly, those contracts, including those referenced in § 100, awarded to MM were fraudulently induced based on those false representations and the government was then *obligated* to pay MM for those contracts. *See Chesbrough*, 655 F.3d at 472 (stating 9(b) may be satisfied where "relator alleges facts from which

it is highly likely that a claim was submitted to the government.”) Lardner has offered facts creating a strong inference that claims were submitted to the Government. That is all that is needed.

E. Lardner Adequately Alleged that S&N Conspired to Violate the FCA.

Lardner’s Complaint alleges that S&N conspired with MM to use MM as a sham small business front to access small business set-aside contracts that neither could procure independently: S&N, because it was too large to qualify as a small business; and MM, because it did not have the ability or resources to distribute the TRUCLEAR product independently.

The Sixth Circuit has long held that conspiracy claims under the FCA are analyzed the same as any civil conspiracy claim under federal law. In *U.S. v. Murphy*, 937 F.2d 1032 (6th Cir. 1991), it analyzed an FCA conspiracy claim, using the elements of civil fraud:

A civil conspiracy is an agreement between two or more persons to injure another by unlawful action. Express agreement among all the conspirators is not necessary to find the existence of a civil conspiracy. . . . All that must be shown is that there was a single plan, that the alleged coconspirator shared in the general conspiratorial objective, and that an overt act was committed in furtherance of the conspiracy that caused injury to the complainant.

Id. Consistent with *Murphy*, courts in this district have required an FCA conspiracy to show that “(1) there was a single plan to get a false claim paid, (2) the alleged coconspirators shared in the general conspiratorial objective to get a false claim paid, and (3) one or more conspirators performed an overt act in furtherance of the conspiracy to get a false claim paid.” *U.S. ex rel. Howard v. Lockheed Martin Corp.*, 499 F. Supp. 2d 972, 980 (S.D. Ohio 2007).

Lardner has offered specific, particular, and plausible facts putting Defendants on adequate notice of his conspiracy claims and those facts are described above at pages 12-13 (including bullet points and Complaint paragraphs) with respect to the small business fraud, and in the Complaint at ¶¶ 6-7 and 119-131 for the Buy American claim. The very fact of the involvement of both S&N and MM in the transactions creates a strong inference of a single shared conspiratorial objective

to get false claims paid. Certainly, they could not have engaged in those transactions without some sort of agreement. And absent S&N's desire to sell its product to the Government when its price point limited sales to small businesses, S&N would have no logical reason to go through the charade of having MM create the invoice for a sale actually executed by S&N. And MM would have no logical reason to be the invoicing entity for S&N sales if there were not an agreement (with a monetary benefit) to use its small business status to procure contracts for purchase of TRUCLEAR by the Government, the execution of which was primarily the work of S&N. Similarly, neither S&N nor MM would go through the charade of claiming the FMS was made in the U.S. if they did not intend to generate a fraudulent sale. The conduct arising from those transactions also constitute overt acts in furtherance of the conspiracy. For example, every time MM submits a bid on a small business set-aside contract or an FMS, it is furthering the conspiracy.

Finally, it is black letter law that, even under Rule 9(b), "[m]alice, intent, knowledge, and other conditions of a person's mind may be alleged generally." *Chesbrough*, 655 F.3d at 466-67; Fed. R. Civ. P. 9(b). As S&N notes, Lardner has alleged that Defendants "acted in concert and intentionally to procure and to seek payment" for fraudulently induced contracts. (¶ 138.) This, plus the particular facts alleged put S&N on notice of the conspiracy claim against it.

S&N mounts two challenges to Lardner's conspiracy claim. Neither warrant dismissal. First, S&N claims that a specific statement where Defendants agree to defraud the Government is required. Def. Mem. at 18. However, the statute makes no such demand (establishing liability when a person "conspires to commit a violation of [the FCA]," 31 U.S.C. 3729(a)(1)(C)); and neither *Murphy* nor *Howard* require an explicit statement. Finally, the case relied on by S&N for this proposition does not make such a statement mandatory in all cases. In *U.S. ex rel. Ibanez v. Bristol-Myers Squibb Co.*, 874 F.3d 905 (6th Cir. 2017), the Court criticized an off-label marketing

claim, and noted “an unusually attenuated” chain linking the misconduct to the “eventual submission of false claims to the government.” *Id.* at 917. It found the conspiracy allegation insufficient due to “[t]he absence of such a conspiratorial statement, *in conjunction with* relators’ failure to adequately plead a violation of any other section of the FCA. *Id.* at 917 (citation omitted).¹⁰ Here sufficient facts support the underlying claims and there is no “unusually attenuated” chain—the conspiracy/fraudulent plan to procure the Contract is directly linked to the submission of a claim for payment. *Ibanez* should be limited to its facts.

Equally without merit is S&N’s second challenge to the conspiracy claim asserting that it identifies the perpetrators of the conspiracy as the corporations rather than specific individuals. Def. Mem. at 19. To the contrary, conduct by specific individuals is identified. *See e.g.* ¶¶ 80-83, 87-88 (S&N sales representatives), 89-90 (Darla Halfacre, MM Support Services Manager), 91 Casey Phoenix, Western Regional Sales Manager). Regardless of the identification of specific corporate representatives, the FCA states that a violation of the FCA occurs, for example, when a “person” engages in a conspiracy to defraud the Government. 31 U.S.C. 3729(a). The Sixth Circuit has unequivocally held that a corporate entity can be such a “person.” stating: “the only reasonable reading of the Supreme Court’s holding in *Stevens* is that corporations are included within the definition of “persons” under the FCA.” *Kreipke v. Wayne State Univ.*, 807 F.3d 768, 782 (6th Cir. 2015) (citing *Vt. Agency of Nat. Res. v. U.S. ex rel. Stevens*, 529 U.S. 765, 780-83 (2000)).

As a court in this Circuit persuasively concluded, the critical question under Rule 9(b) is whether the defendant was put on notice of the alleged conspiracy, not whether the complaint identifies the corporate personnel involved. *See U.S. ex rel. Roby v. Boeing Co.*, 184 F.R.D. 107,

¹⁰*Ibanez* cites a Second Circuit case, also referenced by S&N, that similarly notes the absence of a “statement” in the context of a failure to show any false statements in the underlying claims. *See U.S. ex rel. Ladas v. Exelis, Inc.*, 824 F.3d 16, 27 (2d Cir. 2016).

109-11 (S.D. Ohio 1998) (characterizing the defendant's insistence on the identification of specific persons as "overreaching"). S&N is hard pressed to claim it cannot defend against the conspiracy claim mounted against it and its challenges to the conspiracy claim should therefore be rejected.

IV. CONCLUSION

This Court should deny Smith & Nephew's Motion to Dismiss because Lardner has pled cognizable causes of action under the FCA with the requisite particularity required by Rule 9(b).

In the event the Court grants Smith & Nephew's Motion to Dismiss, Lardner respectfully requests that dismissal be without prejudice for a period of at least sixty days to afford Lardner an opportunity to file a motion for leave to amend under Fed. R. Civ. P. 15, which requires attaching the proposed amended pleading as an exhibit. W.D. Tenn. ECF Attorney User Manual, I.B.6.

Dated: February 20, 2018

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CERTIFICATE OF SERVICE

I certify that on February 20, 2018 a copy of this document was filed using the Court's CM/ECF system. Copies of this document have been served by electronic means on all registered users of the Court's CM/ECF system who have appeared in this case.

s/ Susan M. Coler

Susan M. Coler